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EXAMINER

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ART UNIT PAPER NUMBER

1615

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/771,151
Filing Date: January 26, 2001
Appellant(s): LASIC ET AL.

Jacqueline F. Mahoney
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10-19-2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Claims 1, 3-9 and 16 stand or fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

EP 0 551 169	YAMAMOTO et al	7-1993
WO 98/07409	ABRA et al	2-1998

5,013,556

WOODLE et al

5-1991

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1, 3-6, 8-9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 551 169.

EP discloses a method of preparation of liposomes containing a supersaturated solution of a water-soluble drug (note the abstract, Example 3 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Yamamoto et al fails to teach any of steps (ii), (iii) and (iv). These arguments are not found to be persuasive. First of all, it should be noted that applicant recognizes that Yamamoto et al teach that the drug is either saturated or supersaturated state. According to claim 1, these steps are (ii) preparing from a supersaturated solution of the compound liposomes at selected size interval; (iii) analyzing said liposomes for the presence or absence of precipitated compound; (iv) based on said analyzing, selecting liposomes of a size that corresponds to liposomes having no entrapped precipitated compound. Instant claims do not recite what the 'selected size intervals' are in terms of specific sizes. Yamamoto uses specific population of liposomes (in Example 3 Yamamoto et al teach that the liposome sizes are 100 nm. This implies Yamamoto et al selected liposomes of this size interval meeting the requirement of instant step (ii). The very fact the Yamamoto et al state that the drug is in a supersaturated solution form implies that there is no precipitate (a

Art Unit: 1615

solution does not contain any precipitate). In example 1 (col. 6), Yamamoto teaches the separation of crystallized cisplatin and the dialysis to remove the crystallized cisplatin (lines 16-21). This implies that Yamamoto et al were monitoring (analyzing) the composition for crystals (precipitate) of the drug thus, meeting the requirement of instant step (iii) since the resulting liposomes of sizes 100 nm do not have the precipitated drug, it is construed as their selection of this population of liposomes (instant step (iv)). It should also be pointed out that there is nothing in Yamamoto et al to indicate that the presence or absence of the precipitate was not checked and the very fact Yamamoto et al refers to the drug solution as 'saturated solution or more' implies clearly that there was no precipitate.

2. Claims 1, 3-9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/07409.

WO 98 discloses a method of preparation of liposomes containing supersaturated solution of an active compound. The liposomes further contain a hydrophilic polymer (PEG) (note the abstract, page 2 line 15 through page 3, line 24, page 6, lines 14-26, page 12, lines 4-21, Example 3 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicants' arguments once again pertain to the lack of steps (ii), (iii) and (iv) in the teachings of Abra. These arguments are not found to be persuasive since as with EP, applicants recognize that the reference teaches entrapment of the active agent

Art Unit: 1615

EITHER in the dissolved or precipitated state. Therefore, the same response as above is applicable.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 551 169 in combination with Woodle (5,013,556) of record.

The teachings of EP (Yamamoto) have been discussed above. What is lacking in EP is the inclusion of a hydrophilic polymer in the liposome compositions.

Woodle discloses that the inclusion of a hydrophilic polymer enhances the circulation time of the liposomes (note the abstract).

The inclusion of a hydrophilic polymer in the liposomes of EP references would have been obvious to one of ordinary skill in the art because it enhances the circulation time of the liposomes as taught by Woodle.

Applicants' arguments have been fully considered but are not found to be persuasive. Although applicants admit that Woodle teaches the use of hydrophilic polymer, they argue that it does not overcome the deficiencies of the primary document. Applicant's arguments with regard to the deficiencies EP references have been addressed above.

Art Unit: 1615

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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GSK
February 7, 2005

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